DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 5, 2014

Longfian Scitech Co., Ltd.
c/o Mr. Jun Peng
P&L Scientific, Inc.
6840 SW 45th LN Unit 5
Miami, FL 33155

Re: K131968
Trade/Device Name: OXY.LIFE Oxygen Concentrator, Models Jay-5
Regulation Number: 21 CFR 868.5440
Regulation Name: Oxygen concentrator, portable
Regulatory Class: Class II
Product Code: CAW
Dated: August 1, 2014
Received: August 7, 2014

Dear Mr. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131968

Device Name: The Longfian Oxygen Concentrator, Model Jay-5

Indications for Use:

The Longfian Oxygen Concentrator, Model Jay-5 is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model Jay-5 can be used in a home, institution, vehicle, and various mobile environments. The Longfian Oxygen Concentrator, Model Jay-5 does not nor is it intended to sustain or support life.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _✓_ OR Over-the Counter Use: ____
(Per 21 CFR 801.109)

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510(k) Summary

510(k) summary as required in 21 CFR 807.92 upon which Substantial Equivalence is based:

The Assigned 510(k) Number is: k131968

1. Submitter Information:

- **Sponsor/510(K) Owner:**
  LONGFIAN SCITECH CO., LTD.
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  Date: November 12, 2013

- **Contact Name:**
  Mr. Jun Peng
  P&L SCIENTIFIC, INC.
  6840 SW 45TH LN UNIT 5, MIAMI, FL 33155
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  Fax: (305) 397 0289
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2. Device Name

Trade Name: OXY.LIFE Oxygen Concentrator, Models Jay-5
Common Name: Oxygen concentrator;
Classification Name: Oxygen concentrator, portable;

3. Classification:

Classification: 21 CFR 868.5440; Class II
Product Code: CAW;

4. Predicate Devices:

Yuyue OxygenMax^{TM} 7F-5 Oxygen Concentrator	K083559, Cleared September 4, 2009	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

5. Description of Device

JAY-5 medical oxygen concentrator adopts pressure swing adsorption principle, which can separate oxygen, nitrogen and other gas from the air, at constant temperature. As soon as power is connected, the air is taken in and compressed by oilless air compressor through filtering, then the compressed air goes through the cooler and it is cooled. After that, the air is taken into absorption tower by control valve and the oxygen can be separated in the absorption tower. At the same time, the high purity oxygen is collected into the oxygen tank, and it goes through the flow meter and humidifier, finally the

oxygen that meets medical standards can be supplied. Oxygen is generated by pure physical method.

The concentrator can supply 1-2 patients simultaneously, with steady oxygen flowing out and reliable, adjustable flow. The device is capable of providing oxygen flow up to 5 LPM. The concentration of supplied oxygen is from 90%-96%. The key parts of the generator adopt anti-tiring and anti-aging design, and the planned life of the whole generator reaches up to 20,000 hours. The weight of Jay-5 is around 25kg (~55lbs). There is no influence on indoor oxygen percent during the generator operating.

JAY-5 medical oxygen concentrator contains the following items:

- One (1) Jay-5 Oxygen Concentrator Unit
- One (1) AC Power Supply
- One (1) Nasal Oxygen Tube
- One (1) Humidifier
- One (1) Operation Manual

6. Intended Use

The Longfian Oxygen Concentrator, Model Jay-5 is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model Jay-5 can be used in a home, institution, vehicle, and various mobile environments. The Longfian Oxygen Concentrator, Model Jay-5 does not nor is it intended to sustain or support life.

7. Summary of Comparison in to Technological Characteristics Predicate Device

Name	Predicate device	Subject device
K number	K083559	K131968
Device Trade Name	Yuyue OxygenMax™ 7F-5 Oxygen Concentrator	JAY-5 Medical Molecular Sieve Oxygen Concentrator
Common Name	Oxygen concentrator	Oxygen concentrator
Classification Name	Oxygen concentrator, Portable	Oxygen concentrator, Portable
Indications for use	The YuYue OxygenMax™ 7F-5 Oxygen Concentrator is intended solely for medical use in oxygen therapy programs under the supervision of a physician. It is intended to provide supplemental oxygen to patients with respiratory disorders for use in the home or health care facility. This device is available by prescription only and is not intended to support or sustain life	The Longfian Oxygen Concentrator, Model Jay-5 is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model Jay-5 can be used in a home, institution, vehicle, and various mobile environments. The Longfian Oxygen Concentrator, Model Jay-5 does not nor is it intended to sustain or support life.
Classification	21 CFR 868.5440	21 CFR 868.5440

Feature		
Power supply	AC 220±22V， 50±1Hz	AC 230±23V, 50±1Hz
Input power	500W	500W
Oxygen concentration	90%-94%	93%±3%
Oxygen flow	0.5~5L/min	0~5L/min
Outlet pressure	40~70kPa	40~70kPa
Noise	≤53dB(A)	≤53dB(A)
Fuse	/	T6.3AL/250V
Operating system	Pressure Swing Adsorption	Pressure Swing Adsorption
Electrical classification	Class II Type B	Class II Type B
Dimensions	445×372×680mm	365×375×600mm (14.37"×14.76"×23.62")
Net weight	25.8Kg	26Kg
Alarm	Low & high pressure	Low & high pressure; Power failure
LCD display	Accumulating timing	Accumulating timing; present timing; timing
Accessories	Nasal oxygen cannula Humidifier	Nasal oxygen tube Humidifier
Materials		
Sieve Bed	Synthetic Zeolite	Synthetic Zeolite
Nasal Oxygen Tube	PVC	PVC
Principles of operation		
Operating system	Time cycle/ Pressure Swing Adsorption	Time cycle/ Pressure Swing Adsorption
Electronic safety	Electrical Safety per IEC-60601	Electrical Safety per IEC-60601
Software/Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Operating , transportation and storage environment		
Operating conditions	/	Ambient temperature :10~40℃ Relative humidity:30%~85% Atmospheric pressure:700 1060hPa
Transportation and storage Conditions	/	Ambient temperature :-20~45℃ Relative humidity:≤95% Atmospheric pressure 500-1060hPa

The Longfian Oxygen Concentrator, Model Jay-5 is similar to the predicate devices:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics

- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

Differences between the subject device and predicate do not affect the safety and effectiveness of the device.

8. Assessment of Non-Clinical Testing:

Non-clinical testing of the Longfian Oxygen Concentrator, Models Jay-5 has been performed against requirements for performance, physical attributes, environmental conditions, materials and to provide objective evidence that the device's intended use is met.

9. Summary Performance Data

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety and essential performance, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic
- ISO 8359:1996 Oxygen concentrators for medical use -- Safety requirements
- ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ASTM F 1464-93:2005 Oxygen Concentrators for medical use-Safety Requirements
- Volatile organic compounds (VOC) test per EPA TO-15
- PM 2.5 test per US EPA requirement
- Ozone test per 21 CFR 801.415
- Software validation

10. Conclusion

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is substantially equivalent to the predicate device.